REMARKS

A. Status of the Claims

Claim 1 was pending at the issuance of the present Office Action. Claim 3 is withdrawn as being drawn to non-elected subject matter. Claim 1 is amended.

B. Claim Rejections – 35 USC §103

Claim 1 is rejected under 35 USC §103 as allegedly being unpatentable over Xiao in view of Clark *et al.*

Claim 1 has been amended to more particularly point out that the patient being treated by the method of the claim has been diagnosed as having primary open angle glaucoma. MPEP §2143.03 requires that all claim limitations be considered in an obviousness determination, and the Board of Patent Appeal and Interferences (BPAI) recently confirmed that "obviousness requires a suggestion of all limitations in a claim." *See In re Wada and Murphy*, Appeal 2007-3733, *citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Circ. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). Applicant submits that none of the cited art teaches or suggests the use of the compounds in the present claims to treat primary open angle glaucoma in a patient in need thereof. In particular, it is submitted that the teaching of Clark *et al.* fails to cure the conceded deficiency in Xiao, and that the asserted combination of Xiao and Clark *et al.* therefore fails to render the instant claims obvious.

The Action concedes that Xiao does not teach or suggest the use of histone deacetylase inhibitors for treating primary open angle glaucoma (see page 3 of the Office Action). Nevertheless, the Action rejects the instant claims, asserting that Clark *et al.* provides the necessary disclosure. In particular the Action states that Clark *et al.* teach that treatment of neovascular conditions of the eye includes chronic glaucoma (see page 3 of the Office Action). Thus, the Action contends that the teachings of Xiao and Clark *et al.* render the instant claims obvious. Applicant respectfully traverses this contention.

The Action appears to erroneously characterize primary open angle glaucoma as chronic glaucoma (see Office Action, page 3). Those of skill in the art recognize that primary open angle glaucoma is a subset of chronic glaucoma, which also includes other types of glaucomas. The various types of chronic glaucoma are not identical, and do not necessarily share the same pathophysiology. Neovascular glaucoma and primary open angle glaucoma, for example, are definitely not the same diseases. Consequently, the Action has erred in identifying primary open angle glaucoma as synonymous with chronic glaucoma.

In addition, the instant rejection appears to be based on the Action's conclusion that certain features of the compounds of Clark *et al.* (*i.e.*, substituted hydrindanes), namely the ability to treat neovascular glaucoma and primary open angle glaucoma, can be applied to completely unrelated compounds, such as histone deacetylase inhibitors (see Office Action, page 5). Those of skill in the art will recognize that the ability of a compound to treat both neovascular glaucoma and primary open angle glaucoma is unusual, and is not applicable to every compound that could treat one condition or the other. For example, β-blockers and carbonic anhydrase inhibitors are commonly prescribed to treat primary open angle glaucoma. However, such compounds are not useful for directly affecting the pathogenesis and pathology of neovascular glaucoma. Indeed, Mabuchi *et al.* showed that anti-glaucoma eye drops and carbonic anhydrase inhibitors failed to lower intraocular pressure in patients who were diagnosed as having neovascular glaucoma, and that such patients required multiple laser perforation for effective treatment (Mabuchi *et al.*, 2000, *Jpn. J. Ophthalmol.* 44:392-399; attached hereto as Exhibit A). Therefore, such evidence indicates that compounds used for treating primary open angle glaucoma are not necessarily useful for treating neovascular glaucoma. Consequently, Clark *et al.* cannot be relied upon to support the Action's conclusion that any compound shown to be used for treating one form of glaucoma can be used for the treatment of a different form of glaucoma, and the teachings of Xiao and Clark *et al.* would not have motivated one of skill in the art to consider using the compounds in the present claims to treat primary open angle glaucoma in a patient in need thereof.

In view of the foregoing discussion, Applicant submits that the combination of Xiao and Clark *et al.* do not render Claim 1 obvious. Consequently, Applicant respectfully requests that this ground of rejection be withdrawn.

C. **Double Patenting**

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/697,135. Application No. 10/697,135 is no longer pending. Therefore, this rejection is moot.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 12/609873. Applicant will consider filing a terminal disclaimer when allowable subject matter is found in either this application or the copending application.

CONCLUSION

This is submitted to be a complete response to the outstanding Action. Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

The Examiner is invited to contact the undersigned attorney at (817) 615-5330 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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EXHIBIT A

Pars Plana Filtration with Multiple Laser Perforation of the Uvea for Neovascular Glaucoma Following Proliferative Diabetic Retinopathy

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Purpose: To evaluate the effect of pars plana filtration with multiple laser perforation of the uvea in neovascular glaucoma patients following proliferative diabetic retinopathy.

Methods: In 18 eyes of 13 patients, after a fornix-based conjunctival incision, two 9 × 3 mm, thin, rectangular scleral flaps were created 3–6 mm posterior to the limbus. The remaining layers of sclera under each flap were removed. The exposed uvea was irradiated at a mean of 60.6 spots with an argon laser just to the point of perforation. After the posterior chamber fluid escaped, the flaps were sutured.

Results: The mean preoperative intraocular pressure (IOP) was 36.4 ± 9.0 mm Hg. After an average follow-up of 16.6 ± 5.9 months, the mean final postoperative IOP was 16.6 ± 4.4 mm Hg. The postoperative IOP was below 21 mm Hg in 3 (16.7%) of the 18 eyes without medication, in 14 (77.8%) on anti-glaucoma eye drops, and in 16 (88.9%) on anti-glaucoma eye drops and an oral carbonic anhydrase inhibitor. Snellen visual acuity improved by more than 2 lines in 7 of the 18 eyes, worsened by this amount in 3, and remained within baseline ± 2 lines in 8.

Conclusion: This procedure is an effective treatment for neovascular glaucoma patients following proliferative diabetic retinopathy. **Jpn J Ophthalmol 2000;44:392–399** © 2000 Japanese Ophthalmological Society

Key Words: Neovascular glaucoma, pars plana filtration with laser, proliferative diabetic retinopathy.

Introduction

Neovascular glaucoma following proliferative diabetic retinopathy (PDR) has been treated in a variety of ways, including trabeculectomy, various implant operations, and cyclophotocoagulation. Despite such treatment, however, it is difficult in some patients to completely control the intraocular pressure (IOP) and prevent the deterioration of visual function.

Recently, Hamano et al[1] have reported using cyclophotocoagulation ab externo, in which sclerectomy is combined with direct photocoagulation ab externo to the pars plana. Using this procedure, IOP was controlled in 6 eyes of 5 patients with neovascular glaucoma following PDR. In the present study, we employed a modified version of this procedure and evaluated its effect in controlling IOP in 18 eyes of 13 patients with neovascular glaucoma following PDR.

Materials and Methods

Eighteen eyes of 13 patients (8 men, 11 eyes; 5 women, 7 eyes) with neovascular glaucoma following PDR were evaluated at the Kurihara Eye Hospital. The IOP of these eyes had remained uncontrolled with anti-glaucoma eye drops and an oral carbonic anhydrase inhibitor (acetazolamide). The

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Table 1. Data of Patients Who Had Pars Plana Filtration with Multiple Laser Perforation of Uvea

Patient No.	Age (Years)	Sex	Eye	Grade of Lens	PAS Index	Previous Vitrectomy	Other History	Preoperative IOP (mm Hg)	Postoperative Final IOP (mm Hg)	Preoperative Visual Acuity	Postoperative Final Visual Activity	Mitomycin C Usage	Follow-up (mos)
1	74	F	LE	Pseudophakia	Unknown	+	Uveitis	30	16	0.02	HM	−	16
2	45	M	LE	Phakia	Unknown	−	−	34	13	0.02	0.04	−	18
3	64	F	LE	Aphakia	Unknown	+	Buckling for RD	45	7	HM	LP	+	11
4	66	M	LE	Pseudophakia	1	−	−	52	18	0.07	0.05	−	11
5	50	M	RE	Pseudophakia	Unknown	+	−	30	27	0.2	0.2	+	12
6	48	F	RE	Pseudophakia	0.8	+	−	26	16	0.6	0.4	+	17
7	18	M	RE	Aphakia	1	+	Trabeculectomy	36	23	0.4	0.4	+	15
8	63	M	LE	Pseudophakia	1	−	−	60	34	HM	0.04	−	32
8	65	M	RE	Pseudophakia	1	−	Capsulotomy	33	19	0.06	0.08	+	16
9	52	M	RE	Aphakia	1	+	−	50	34	0.06	0.5	−	23
9	52	M	LE	Aphakia	0.5	+	−	36	15	0.1	0.5	−	23
10	44	M	RE	Phakia	0.4	−	−	55	18	0.2	0.08	−	21
10	45	M	LE	Pseudophakia	0.8	+	−	30	18	0.04	0.08	+	15
11	58	F	RE	Pseudophakia	0	+	−	30	17	0.6	1	−	20
11	58	F	LE	Pseudophakia	0.2	+	−	28	17	0.5	1	−	20
12	43	F	RE	Pseudophakia	1	+	Diabetic keratopathy	34	14	HM	0.09	−	10
12	43	F	LE	Pseudophakia	1	−	Diabetic keratopathy	32	12	0.1	0.03	+	13
13	44	M	RE	Pseudophakia	0	+	−	32	20	0.3	0.4	−	6

PAS: peripheral anterior synechia; IOP: intraocular pressure; LE: left eye; RE: right eye; HM: hand motion; RD: retinal detachment; LP: light perception.

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average age was 51.8 ± 12.7 years (range, 18–74 years). Panretinal photocoagulation had been performed in all 18 eyes; vitrectomy in 12 eyes. Four eyes were aphakic; 12 pseudophakic (Table 1). Informed consent was provided by each patient.

The patients received retrobulbar anesthesia consisting of 2% lidocaine hydrochloride without epinephrine. A superior limbal peritomy was made with relaxing incisions as needed to involve the two superior quadrants. Dissection was carried to at least 8 mm posterior to the limbus. Superficial bleeding vessels were cauterized lightly with monopolar or bipolar cautery. Two 9 × 3 mm, thin, rectangular scleral flaps, with the base towards the fornix, were created 3–6 mm posterior to, and with the long axis parallel to the limbus (Figure 1, top left). The eyes undergoing a vitrectomy had smaller scleral flaps than those without a previous vitrectomy because of the sclerotomy over pars plana from the previous vitrectomy. These flaps were dissected as thinly as possible. A surgical sponge soaked with 0.02% mitomycin C was applied on the scleral flaps for 5 minutes in 7 eyes that had proved difficult to treat because they had had prior operations or were those of younger patients. After the sponge was removed, the surgical site was irrigated with balanced saline solution. The remaining layers of sclera under each flap were removed over the pars plana (Figure 1, top right, and Figure 2). Using an argon laser (Endocoagulator Model MEE-648, HGM Medical Laser Systems, Inc. 3959 West 1820 South Salt Lake City, Utah 84104; power, 500–700 mW; duration, 1 second to such time as the uvea became perforated), a mean of 60.6 burns (range, 17–136 burns) just to the point of multiple perforation were applied to the exposed uvea of each eye. Each flap contained about 8–12 slightly touching perforation spots (Figure 1, bottom left, and Figure 3). Laser exposure was repeated to the same area until that area became perforated. In the first patients, the repeated laser burns were placed with exposure of 500 mW for 1 second. In patients thereafter, fewer burns were necessary when applied with 700 mW of power for longer exposure times. After the posterior chamber fluid escaped, the scleral flaps were closed

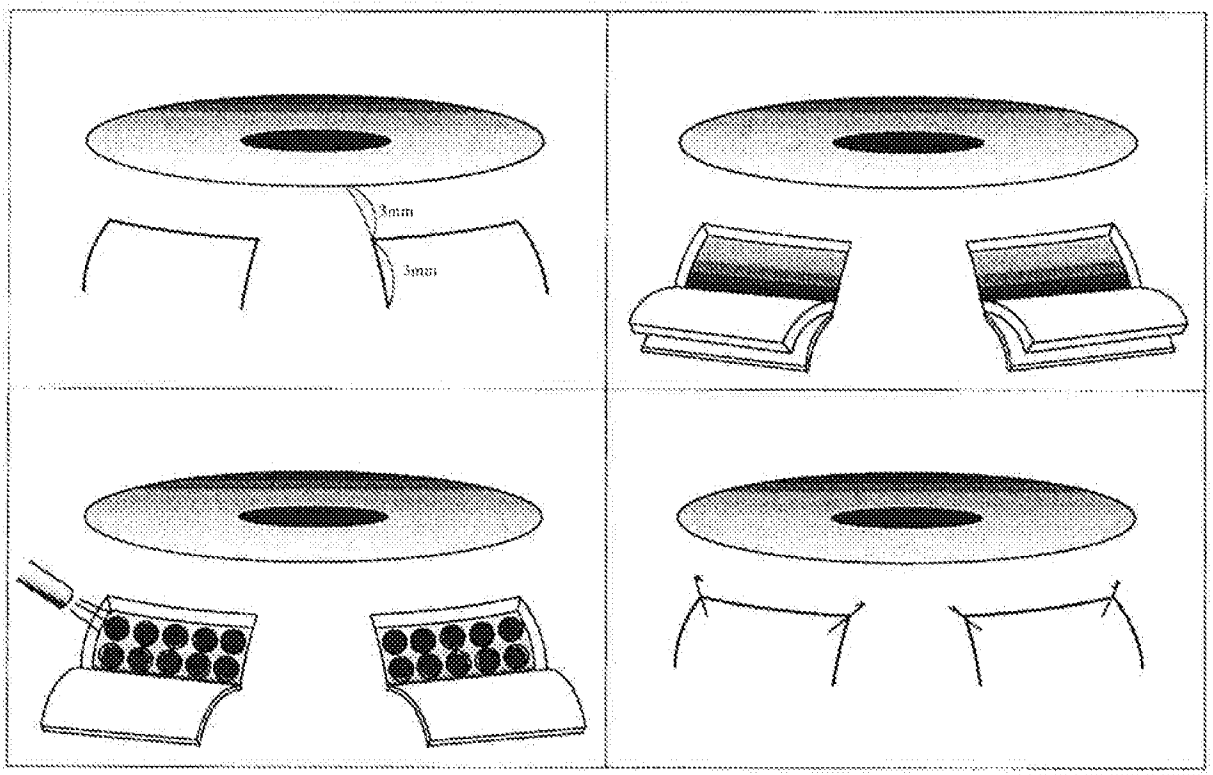

Figure 1. Schema of surgical method. Top left: Two 9 × 3 mm, thin, rectangular scleral flaps with fornix base were created 3–6 mm posterior along limbus. Top right: Remaining layers of sclera under each flap were removed over pars plana. Bottom left: Exposed uvea was irradiated with argon laser. Bottom right: Scleral flaps were closed with interrupted 10-0 nylon sutures.

with interrupted 10-0 nylon sutures (Figure 1, bottom right), using 2–4 sutures per flap. Suture tension was adjusted to allow a slow leak of posterior chamber fluid at the margins of the scleral flap. The conjunctival incision was closed with a running 10-0 nylon suture. Reconstruction had been performed in 7 eyes. After fornix-based conjunctival incision, the exposed scleral flaps were reopened and, if necessary, laser exposure was added. After enough posterior chamber fluid had escaped, the scleral flaps and conjunctiva were sutured. Postoperative care included administration of topical prednisolone acetate, topical 1% atropine, topical antibiotics, and systemic antibiotics. All procedures were performed by one surgeon.

Results

The mean preoperative IOP was 36.4 ± 9.0 mm Hg with anti-glaucoma medications. After an average follow-up of 16.6 ± 5.9 months (range, 6–32 months), the final mean postoperative IOP was 16.6 ± 4.4 mm Hg (Figure 4). The mean IOP before surgery was significantly higher than those taken at any of the postoperative visits (Figure 5). The postoperative IOP was below 21 mm Hg in 3 (16.7%) of the 18 eyes without medication, in 14 (77.8%) on anti-glaucoma eye drops, and in 16 (88.9%) on anti-glaucoma eye drops and an oral carbonic anhydrase inhibitor (acetazolamide) (Table 2).

Snellen visual acuity improved by more than 2 lines in 7 eyes because of the disappearance of corneal edema in 3, improved diabetic keratopathy in 1, and improved diabetic retinopathy in 3; worsened by this amount in 3 because of ischemic optic neuropathy, prolonged diabetic keratopathy due to mitomycin C, and the recurrence of uveitis; and remained within baseline ±2 lines in 8 (Figure 6).

Postoperative early complications included vitreous hemorrhage in 3 eyes, hyphema in 4, increased diabetic keratopathy in 2 (1 patient), and choroidal detachment in 1. Choroidal detachment and vitreous hemorrhage in 2 eyes disappeared within a few weeks and diabetic keratopathy in 1 improved gradually. Transient IOP increase of more than 25 mm Hg within a postoperative week occurred in 3 eyes. Fibrin formation was found in some eyes but disappeared soon after the early follow-up. There were no cases of severe eye pain, flat anterior chamber, leakage of aqueous humor, or hypotonic maculopathy (Table 3). Chronic complications included aftercataract in 1 eye and capsulotomy was performed. Except for a vitreous hemorrhage that developed in 1 eye during early follow-up, and prolonged diabetic

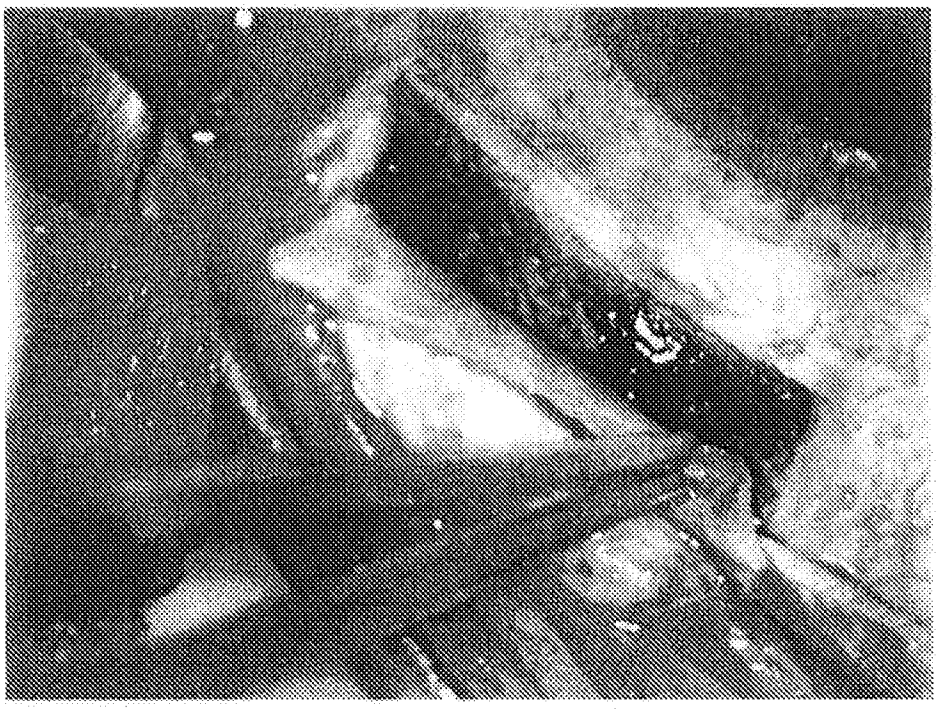

Figure 2. Photograph of scleral wounding during surgery. Remaining inner layers of sclera under each flap were removed.

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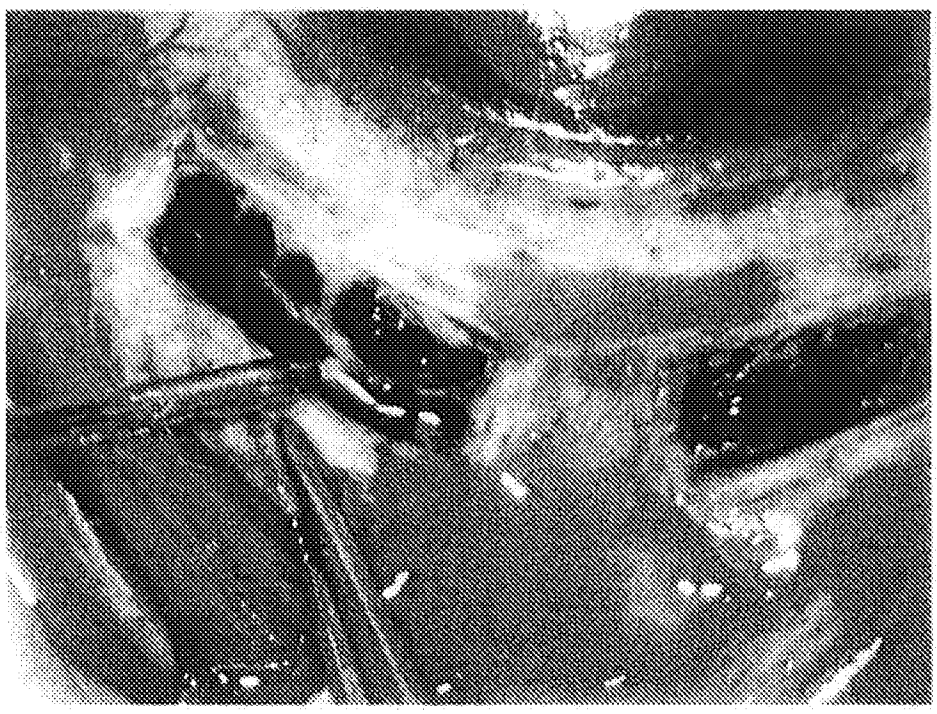

Figure 3. Photograph of scleral wound during surgery. Exposed uvea was irradiated with argon laser.

keratopathy in another, likely due to the intraoperative use of mitomycin C, none of these complications significantly affected visual function. Typical large cystic bleb was observed in only 1 eye using mitomycin C. Aqueous humor may have been filtrated to a posterior site in the other cases. There was no relationship between apparent bleb formation, application of mitomycin C, and IOP reduction.

Discussion

The IOP in some cases of neovascular glaucoma after PDR remains uncontrolled despite panretinal photocoagulation, retinal cryopexy, and vitrectomy. The results of trabeculectomy for refractory glaucoma have been improved with the intraoperative application of mitomycin C.[2–4] But in some cases, the IOP is difficult to control with trabeculectomy, especially in cases of neovascular glaucoma or in those with severe conjunctival scars. Two surgical treatments have been applied to refractory cases without notable success. One decreases the aqueous production by partially damaging the ciliary body. The other attempts to facilitate drainage of aqueous humor. Cyclophotocoagulation and some kinds of implant procedures for the latter have often been performed for refractory glaucoma. In the United States, the implant procedure has often been performed for refractory cases. However, in Japan, the implant procedure is not popular because it is not reimbursable under national health insurance.

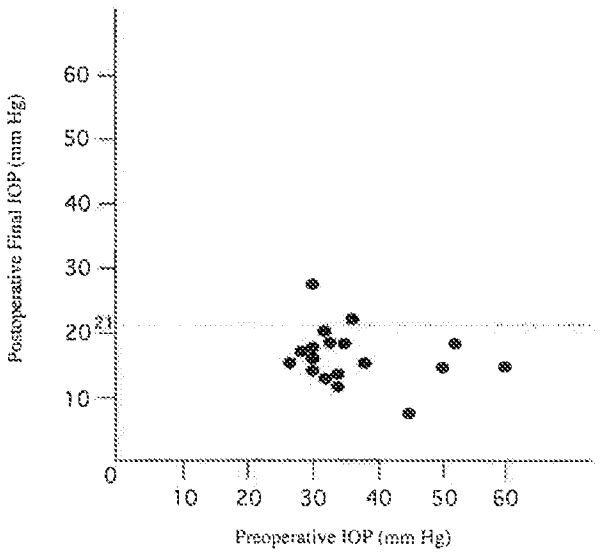

Figure 4. Comparison of preoperative and final intraocular pressure (IOP). Mean preoperative final IOP was 36.4 ± 9.0 mm Hg (± SD). Average follow-up of 16.6 ± 5.9 months (range, 6–32 months). Mean final postoperative IOP was 16.4 ± 4.2 mm Hg.

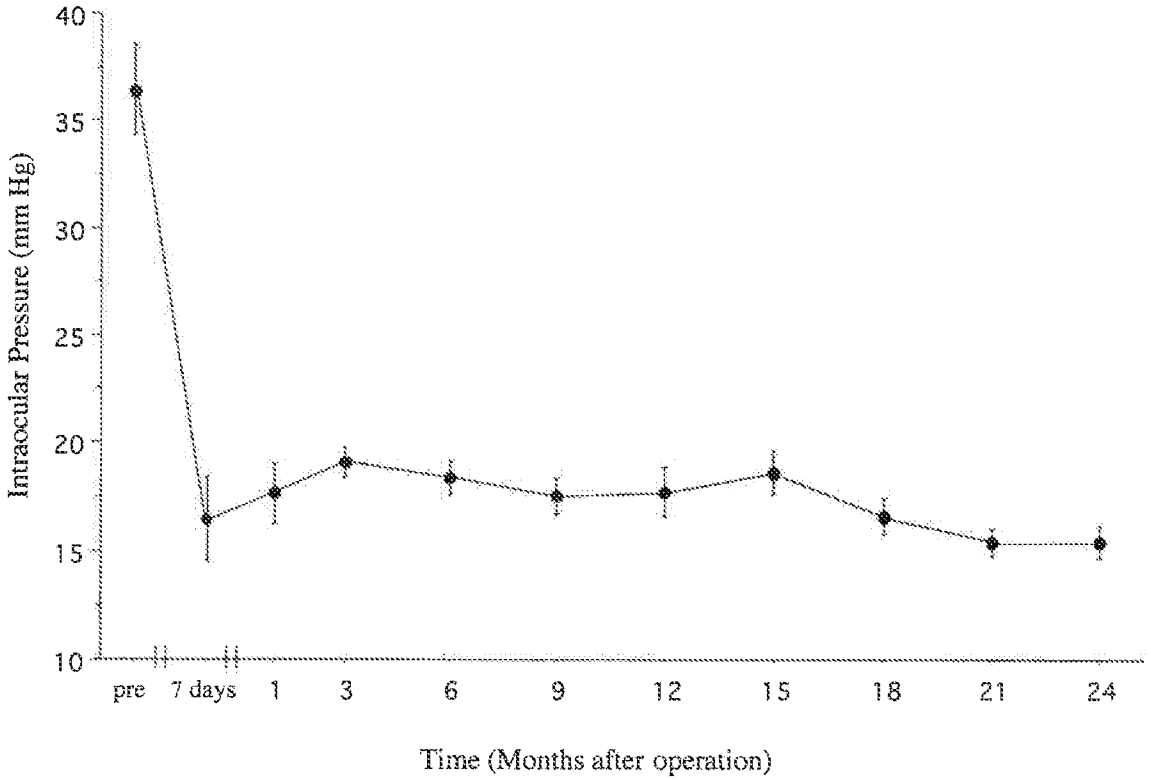

Figure 5. Mean intraocular pressure (IOP) versus postoperative time. There was reduction in IOP at all follow-up intervals (± SE).

It has been reported that the success rates for the treatment of refractory glaucomas by cyclophotocoagulation or implant procedures range from 20% to 90%.[5–27] Previous reports have also described that eyes treated by cyclophotocoagulation have some complications, such as phthisis and visual loss, and that eyes treated by implant surgery have some complications, such as a flat anterior chamber, a blocked tube, endothelial damage due to tube-cornea friction, implant plate erosion, and extraocular motility disturbances.[5–30] Simon et al[31] have reported that implant procedures might be associated with significant retinal complications and subsequent visual loss. On the other hand, success rates for treatment with the present procedure have ranged from 70% to 100% in several series, and there have been no severe complications.[1,32,33] In fact, operative methods in previous studies were partially different from those in the present study. Hamano et al[1] have reported that the operative method in their study used scleral flaps with a base perpendicular to the limbus, not parallel as in the fornix-based methods in the present study. These perpendicular based scleral flaps were created and 20–50 burns (power, 350–500 mW; duration, 0.5 seconds) with argon laser were applied to the exposed uvea of each eye. Photocoagulated spots on the exposed uvea seem, for the most part, not to be perforated. Mitomycin C was not applied. Machida et al[32] and Iwaki[33] have reported that limbal base scleral flaps were created and 50 burns (power, 500 mW; duration, 0.5 seconds) with argon laser were applied to the exposed uvea of each eye. Mitomycin C was not applied. Stephen et al[34] first reported the operative method of a pars plana filtering procedure

Table 2. Success Rate of Operation

	No. of Eyes*
Success†	3/18 (16.7)
Qualified success‡	
With only anti-glaucoma eye drops	11/18 (61.1)
With eye drops and oral carbonic anhydrase inhibitor	2/18 (11.1)
Total	16/18 (88.9)

*Values in parentheses are percentages.
†Success indicates intraocular pressure < 21 mm Hg without medication.
‡Qualified success indicates intraocular pressure < 21 mm Hg with anti-glaucoma medication.

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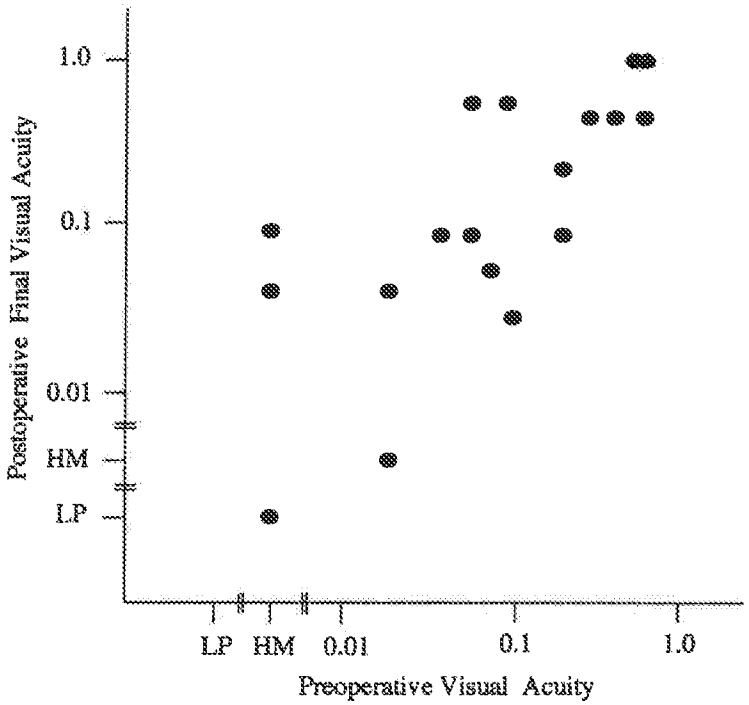

Figure 6. Comparison of preoperative and final visual acuities. Snellen visual acuity improved by more than 2 lines in 7 eyes, worsened by this amount in 3, and remained within baseline ± 2 lines in 8. HM: hand motion; LP: light perception.

combined with lensectomy and vitrectomy for neovascular glaucoma. This procedure was different from our procedure in the following points: a 6 × 3 mm limbal base scleral flap was created, the remaining layer of sclera under the flap was not removed, a 20-gauge puncture wound through the remaining sclera and choroid into vitreous was made and enlarged to 4.5 mm with a sclerotome, the anterior lip was removed with a scleral punch, choroid was trimmed with a scissors not an argon laser to the size of the scleral opening, and mitomycin C was not applied. In the present study, we also concluded that none of the complications significantly affected visual function, except for the vitreous hemorrhage that appeared in 1 eye during early follow-up. There were no cases of flat anterior chamber, leakage of aqueous humor, or hypotonic maculopathy.

Table 3. Early Complications

	No. of Eyes*
Hyphema	4 (22.2)
Vitreous hemorrhage	3 (16.7)
Transient intraocular pressure increase > 25 mm Hg within a postoperative week	3 (16.7)
Increased diabetic keratopathy	2 (11.1)†
Choroidal detachment	1 (5.6)
Flat anterior chamber	0 (0)
Leakage of aqueous humor	0 (0)
Hypotonic maculopathy	0 (0)

*Values in parentheses are percentages.
†In both eyes of 1 patient.

The operation used in the present study is best characterized as a filtering procedure. An extensive filtering bleb may be created by perforating the exposed uvea with argon laser. The IOP reduction, though, has been achieved in most patients without apparent bleb formation. It is difficult to evaluate exactly whether filtration is performed or not because aqueous humor may be filtrated to the posterior site. Another explanation for the IOP reduction might be the increase in uveo-scleral outflow.[35]

The present procedure seems to pose less of a risk of fibrous binding between the scleral flaps and the uvea for the following reasons: the flaps are large and thin, and a wide area of thick sclera has been removed beneath the flaps. However, presumably because of the more severe fibrosis, the success rate in younger patients in the present study (despite the application of mitomycin C) tended to be lower than that in older patients.

Although this operation was expected to be more effective in eyes without vitreous than in eyes with vitreous due to blocked drainage, the difference in the success rate between the eyes with vitreous and those without vitreous did not reach statistical significance ($P = .64$, Fisher's exact test). Although Iwaki[33] has reported that this operation is more effective in eyes without vitreous than in eyes with vit-

reous, a definite conclusion cannot be drawn from the rather small number of eyes in both studies.

Although in a few of our patients the visual function deteriorated postoperatively, on the whole, the visual function of most patients either remained unchanged or improved. We, therefore, conclude that pars plana filtration with multiple laser perforation of the uvea is an effective treatment for neovascular glaucoma patients following PDR.

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